



# NEWAY SINOPHC TECH. LIMITED

ADD:RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE.  
Email:marketing01@newayphc.com; Phone:+86-021-50350029 <https://www.newayphc.com>

## Safety Data Sheet (MSDS)

According to GB/T 16483 and GB/T 17519; Adapts to GHS, IMDG, IATA Standards

Revision Date: 28 FEB 2026

### SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

#### 1.1 Product Identifiers

- Product Name: Vortioxetine Hydrobromide
- Product Number: VOR-20260228
- Brand: SIGALD
- CAS-No.: 936128-06-4
- Synonyms: 1-[2-(2,4-Dimethylphenylsulfanyl)phenyl]piperazine hydrobromide; Trintellix

#### 1.2 Supplier Details

- Company: NEWAY SINOPHC TECH. LIMITED
- Address: RM. 204, BUILDING 3, NO. 188, AONA RD., CHINA (SHANGHAI) PILOT FREE TRADE ZONE
- Telephone: +86-021-50350029
- Fax: +86-021-50350029

#### 1.3 Emergency Telephone

- Emergency Phone #: +86-021-50350029 (CHEMTREC)

#### 1.4 Identified Uses & Uses Advised Against

- Identified Uses: Pharmaceutical raw material for antidepressant drug production (serotonin modulator and stimulator)
- Uses Advised Against: Direct human consumption; unauthorized pharmaceutical formulation; non-pharmaceutical use; veterinary use without official approval

### SECTION 2: Hazards Identification

<b>Summary of Emergency Measures</b>	<b>White crystalline powder. Harmful if swallowed; causes serious eye irritation; affects central nervous system. Inhalation: Move to fresh air, rest. Skin contact: Rinse with water for 10 mins. Eye contact: Rinse for 10-15 mins, seek medical help. Swallowing: Rinse mouth, do not induce vomiting, call poison center immediately. Non-combustible; no explosion risk.</b>
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#### 2.1 GHS Classification

- Acute toxicity, oral (Category 4); Eye irritation (Category 2); Specific target organ toxicity (single exposure), central nervous system (Category 3); Aquatic toxicity (Category 3)

#### 2.2 GHS Label Elements

- Hazard Pictograms: (Exclamation mark)
- Signal Word: **Warning**
- Hazard Statements:
  - H302: Harmful if swallowed
  - H319: Causes serious eye irritation
  - H335: May cause respiratory irritation; affects central nervous system

- H402: Harmful to aquatic organisms
- Precautionary Statements:
- P261: Avoid breathing dust
- P264: Wash hands thoroughly after handling
- P270: Do not eat, drink or smoke when using
- P280: Wear protective gloves/eye/face protection
- P301+P312: If swallowed: Call a POISON CENTER/doctor if unwell
- P305+P351+P338: If in eyes: Rinse cautiously with water, remove contact lenses, continue rinsing
- P391: Collect spillage

## 2.3 Physical and Chemical Hazards

- Non-combustible; no explosive/oxidizing properties; no hazardous decomposition under normal conditions

## 2.4 Health Hazards

- Acute: Gastrointestinal discomfort (swallowed); dizziness/headache (CNS); severe eye irritation; mild respiratory irritation from dust inhalation

- Chronic: No known chronic toxic effects at occupational exposure levels

## 2.5 Environmental Hazards

- Harmful to aquatic organisms; low biodegradability; no significant bioaccumulation potential

## 2.6 Other Hazards

- No additional hazards identified

## SECTION 3: Composition/Information on Ingredients

- Substance: Pure chemical compound (100% Vortioxetine Hydrobromide) | Component | CAS-No. | Concentration (w/w) | Classification | | --- | --- | --- | --- | | Vortioxetine Hydrobromide | 936128-06-4 | 100% | Acute oral toxicity Cat4; Eye irritation Cat2 | | Formula |  $C_{18}H_{22}BrN_3O$  | - | Molecular Weight: 376.29 g/mol |

## SECTION 4: First Aid Measures

### 4.1 First-Aid Measures

- Inhaled: Move victim to fresh air and place in a comfortable position. Consult a doctor if dizziness, cough or chest tightness persists.
- Skin Contact: Remove contaminated clothing and rinse skin with running water for 10 minutes. Wash clothing before reuse.
- Eye Contact: Rinse eyes thoroughly with plenty of running water for 10-15 minutes (hold eyelids open). Remove contact lenses if present. **Seek immediate medical attention** if irritation or redness lasts.
- Swallowed: Rinse mouth with water. Do not induce vomiting. Call a poison center or doctor immediately and provide the product label.

### 4.2 Most Important Symptoms

- Acute: Nausea, headache, dizziness (CNS effects); eye redness, tearing and irritation; mild cough from dust inhalation

### 4.3 Medical Attention



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- Symptomatic treatment required; monitor CNS function for acute ingestion; no specific antidote (supportive care only)4.4 Notes to Physician
- Inform the physician of vortioxetine hydrobromide exposure; monitor vital signs and neurological status

## SECTION 5: Firefighting Measures

5.1 Extinguishing Media: Water spray, foam, carbon dioxide (CO<sub>2</sub>), dry powder (all suitable)5.2 Special Hazards from Combustion: Non-combustible; no hazardous combustion gases or fumes generated under fire conditions5.3 Firefighter Advice: Wear standard fire-fighting gear and a dust mask; avoid inhalation of dust from fire-related disturbance; keep containers cool with water spray if exposed to fire

## SECTION 6: Accidental Release Measures

6.1 Personal Precautions: Wear full PPE (nitrile gloves, chemical safety goggles, N95 dust mask, lab coat); ensure good ventilation; evacuate non-essential personnel from the spill area6.2 Environmental Precautions: Prevent spillage from entering drains, rivers or groundwater; collect spilled material to avoid aquatic contamination6.3 Containment & Clean-Up

- Small Spill: Sweep up with a clean brush and transfer to a sealed HDPE container for professional disposal
- Large Spill: Contain with plastic dikes; transfer to sealed drums with a clean shovel; clean the area with a small amount of water and collect wash water for disposal6.4 Reference: See Section 13 for waste disposal guidelines

## SECTION 7: Handling and Storage

### 7.1 Safe Handling

- Operate in a well-ventilated, dust-free GMP workshop; use closed handling/transfer systems to avoid dust generation and inhalation
- Avoid contact with strong acids, strong bases and high-temperature environments (>60°C) to prevent structural degradation
- Hygiene Measures: Wash hands and face thoroughly after handling; no eating/drinking/smoking in the work area7.2 Safe Storage
- Storage Conditions: Cool, dry, well-ventilated warehouse (≤25°C); keep container tightly sealed; avoid direct sunlight and high humidity (>60%)
- Incompatibilities: Strong acids (HCl/H<sub>2</sub>SO<sub>4</sub>), strong bases (NaOH/KOH), oxidizing agents
- Storage Class (TRGS 510): 6.1 (Toxic Solids)
- Shelf Life: 24 months (unopened, under specified storage conditions)
- Segregation: Store separately from food, feed and non-pharmaceutical materials; keep away from children and unauthorized personnel

## SECTION 8: Exposure Controls/Personal Protection

8.1 Control Parameters: Occupational Exposure Limit (OEL) – TWA 0.2 mg/m<sup>3</sup> (respirable dust) (EU/China proposed)8.2 Exposure Controls

- Engineering Controls: Local exhaust ventilation (LEV) with high-efficiency dust collection; dust-free workbench (pharmaceutical grade)
- Personal Protective Equipment (PPE):
  - Eye/Face: Chemical safety goggles + face shield (mandatory for all handling)
  - Skin: Nitrile rubber gloves ( $\geq 0.11$  mm) + chemical-resistant lab coat + disposable arm covers
  - Respiratory: N95 dust mask (normal handling); powered air-purifying respirator (PAPR) for high-dust environments
  - Hand: No bare hand contact; replace gloves immediately if damaged or contaminated

## SECTION 9: Physical and Chemical Properties

- Physical State: White to off-white crystalline powder | Odor: Practically odorless
- Melting Point: 178-182°C | Boiling Point: Decomposes before boiling ( $>200^\circ\text{C}$ )
- Flammability: Non-combustible | Flash Point: Not applicable
- Autoignition Temperature:  $>400^\circ\text{C}$  | Decomposition Temperature:  $\geq 200^\circ\text{C}$
- pH Value: 4.0-6.0 (0.5% aqueous suspension, 25°C) | Water Solubility: Sparingly soluble (2.3 g/100 mL, 25°C)
- Methanol Solubility: Soluble ( $\geq 10$  g/100 mL, 25°C) | Density (25°C): 1.38 g/cm<sup>3</sup>
- Vapor Pressure (25°C):  $<0.0001$  hPa | Particle Size: 90% passing 100 mesh (pharmaceutical grade)
- Explosive Properties: None | Oxidizing Properties: None
- Hygroscopy: Slight | Optical Rotation:  $0^\circ \pm 1^\circ$  (racemic mixture)

## SECTION 10: Stability and Reactivity

10.1 Chemical Stability: Stable under recommended storage conditions ( $\leq 25^\circ\text{C}$ , dry, sealed); slight hygroscopy with no chemical degradation

10.2 Hazardous Reactions: No hazardous reactions under normal use and handling conditions

10.3 Conditions to Avoid: High temperature ( $>60^\circ\text{C}$ ), direct sunlight, high humidity ( $>60\%$ ), strong acids/bases, oxidizing agents

10.4 Incompatible Materials: Concentrated hydrochloric acid, sulfuric acid, sodium hydroxide, hydrogen peroxide (30%+)

10.5 Hazardous Decomposition Products: No hazardous decomposition products; thermal decomposition at high temperature releases non-toxic organic and inorganic compounds

## SECTION 11: Toxicological Information

### 11.1 Toxicological Effects

- Acute Toxicity: Oral (Rat, LD<sub>50</sub>) = 1250 mg/kg; Dermal (Rabbit, LD<sub>50</sub>)  $>2000$  mg/kg; Inhalation (Rat, LC<sub>50</sub>)  $>5$  mg/m<sup>3</sup> (4h)
- Skin Irritation: No irritation (Rabbit, 4h exposure)
- Eye Irritation: Category 2 (severe redness and tearing, reversible in 72h; Rabbit, 24h exposure)
- Mutagenicity: Negative (Ames test, chromosome aberration test)
- Carcinogenicity: IARC Class 3 (not classifiable as carcinogenic to humans)



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- Reproductive Toxicity: No reproductive harm at normal occupational exposure; high doses cause mild fetal developmental changes (animal studies)
- CNS Toxicity: Dose-dependent dizziness, headache and somnolence at high exposure levels

## SECTION 12: Ecological Information

12.1 Toxicity: Zebrafish (LC<sub>50</sub>) = 38 mg/L (96h); Daphnia (EC<sub>50</sub>) = 25 mg/L (48h); Algae (EC<sub>50</sub>) = 45 mg/L (72h)  
12.2 Persistence & Degradability: Moderate biodegradability (BOD<sub>5</sub>/COD = 0.4-0.5) in aquatic environments; degrades within 45 days  
12.3 Bioaccumulative Potential: Low (Log P = 2.1); no significant accumulation in aquatic organisms  
12.4 Mobility in Soil: Low (binds to soil organic matter; no leaching to groundwater under normal conditions)  
12.5 PBT/vPvB: Not classified as PBT/vPvB  
12.6 Other Adverse Effects: Temporary inhibition of aquatic organism feeding behavior at high concentrations; no long-term ecological harm

## SECTION 13: Disposal Considerations

13.1 Waste Treatment

- Product Waste: Classified as hazardous pharmaceutical waste; incinerate at licensed hazardous waste incineration facilities (≥1200°C) with gas treatment
  - Packaging Waste: Rinse packaging with a small amount of methanol; collect rinsate for hazardous waste treatment; dispose of packaging as hazardous waste
- 13.2 Disposal Regulations: Comply with China HW02 (Medical Waste) and Basel Convention; do not dispose with municipal solid waste or aquatic environments

## SECTION 14: Transport Information

14.1 UN Number: UN 2811  
14.2 UN Proper Shipping Name: Toxic solids, organic, n.o.s. (Vortioxetine Hydrobromide)  
14.3 Transport Hazard Class: 6.1 (Toxic Substances) | Packaging Group: III  
14.4 Environmental Hazards: Marine Pollutant (No)  
14.5 Special Transport Precautions: Transport at ≤25°C; use sealed HDPE/fiber drums; mark with GHS hazard labels + UN 2811; avoid direct sunlight and high humidity; do not transport with strong acids/bases/oxidizing agents

## SECTION 15: Regulatory Information

15.1 National & International Regulations

- China: NMPA Pharmaceutical Raw Material; Pharmacopoeia (2020); Hazardous Chemicals List (2015)
  - EU: REACH Registered; Ph. Eur. 10.0 compliant; ECHA non-SVHC
  - US: TSCA Listed; USP 45 compliant; FDA-regulated pharmaceutical raw material
- 15.2 Other: Comply with local pharmaceutical manufacturing, GMP and hazardous waste disposal regulations

## SECTION 16: Other Information

- This MSDS complies with GB/T 16483, GB/T 17519 and GHS Rev.9; based on current scientific and regulatory knowledge



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- Supplier is not liable for damage caused by improper handling, storage, use or non-compliance with safety precautions
- For additional technical or regulatory information, contact the supplier's pharmaceutical technical department

